occur. Documentation of such reports shall be retained in MDR files for time periods specified in § 803.18.

(2) The manufacturer or importer determines that the device was manufactured or imported by another manufacturer or importer. Any reportable event information that is erroneously sent to a manufacturer or importer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured or imported by that firm.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart C—User Facility Reporting Requirements

§ 803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by § 803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under § 803.14, and if the identity of the manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by § 803.32, on FDA Form 3500A or electronic equivalent, as approved under § 803.14, to the manufacturer of the device. If the identity of the manufacturer is not known, the report shall be submitted to FDA.

(b) *Information that is reasonably known to user facilities.* User facilities must provide all information required in this subpart C that is reasonably known to them. Such information includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable followup within the facility. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

§ 803.32 Individual adverse event report data elements.

User facility reports shall contain the following information, reasonably known to them as described in 803.30(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests including dates and laboratory data; and

(7) Description of other relevant history including pre- existing medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;
(3) Manufacturer name and address;
(4) Operator of the device (health professional, patient, lay user, other);
(5) Expiration date;
(6) Model number, catalog number, serial number, lot number, or other identifying number;
(7) Date of device implantation (month, day, year);
(8) Date of device explantation (month, day, year);
(9) Whether device was available for evaluation and whether device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and
(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)
(d) Initial reporter information (Block E) shall contain the following:
(1) Name, address, and telephone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;
(2) Whether the initial reporter is a health professional;
(3) Occupation; and
(4) Whether initial reporter also sent a copy of the report to FDA, if known.
(e) User facility information (Block F) shall contain the following:
(1) Whether reporter is a user facility;
(2) User facility number;
(3) User facility address;
(4) Contact person;
(5) Contact person's telephone number;
(6) Date the user facility became aware of the event (month, day, year);
(7) Type of report (initial or followup (if followup, include report number of initial report));
(8) Date of the user facility report (month, day, year);
(9) Approximate age of device;
(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');
(11) Whether a report was sent to FDA and the date it was sent (month, day, year);
(12) Location, where event occurred;
(13) Whether report was sent to the manufacturer and the date it was sent (month, day, year); and
(14) Manufacturer name and address; if available.

§ 803.33 Annual reports.

(a) Each user facility shall submit to FDA an annual report on FDA Form 3419, or electronic equivalent as approved by FDA under § 803.14. Annual reports shall be submitted by January 1 of each year. The annual report and envelope shall be clearly identified and submitted to FDA with information that includes:
(1) User facility's HCFA provider number used for medical device reports, or number assigned by FDA for reporting purposes in accordance with § 803.3(ee);
(2) Reporting year;
(3) Facility's name and complete address;
(4) Total number of reports attached or summarized;
(5) Date of the annual report and the lowest and highest user facility report number of medical device reports submitted during the report period, e.g., 1234567890–1995–0001 through 1000;
(6) Name, position title, and complete address of the individual designated as the facility contact person responsible for reporting to FDA and whether that person is a new contact for that facility; and
(7) Information for each reportable event that occurred during the annual reporting period including:
(i) User facility report number;
(ii) Name and address of the device manufacturer;
(iii) Device brand name and common name;
(iv) Product model, catalog, serial and lot number;
(v) A brief description of the event reported to the manufacturer and/or FDA; and
(vi) Where the report was submitted, i.e., to FDA, manufacturer, distributor, importer, etc.
(b) In lieu of submitting the information in paragraph (a)(7) of this section, a user facility may submit a copy of FDA Form 3500A, or an electronic equivalent as approved under section 803.14, for each medical device report submitted to FDA and/or manufacturers by that facility during the reporting period.